

# EXHIBIT 17



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/103,324	12/11/2013	Declan Walsh	TEVE-139US1	3830

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RATNERPRESTIA  
P.O. BOX 980  
VALLEY FORGE, PA 19482

EXAMINER
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HESS, DANIEL A

ART UNIT	PAPER NUMBER
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2876

NOTIFICATION DATE	DELIVERY MODE
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12/07/2015

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PCorrespondence@ratnerprestia.com

**Office Action Summary**Application No.  
14/103,324Applicant(s)  
WALSH ET AL.Examiner  
DANIEL HESSArt Unit  
2876AIA (First Inventor to File)  
Status  
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 8/10/2015.  
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims\***

- 5) ☒ Claim(s) 1-10 is/are pending in the application.  
5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 1-10 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

\* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).

**Application Papers**

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

**Certified copies:**

- a) ☐ All b) ☐ Some\*\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)  
Paper No(s)/Mail Date \_\_\_\_.
- 3) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Other: \_\_\_\_.

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### **DETAILED ACTION**

This action is responsive to applicant's amendment and arguments of 11/4/2015, which have been entered into the electronic file of record.

The present application is being examined under the pre-AIA first to invent provisions.

#### ***Response to Amendments and Arguments***

The examiner is of the view that the applied prior art of Morton and Davies teaches the essential elements of the claimed inhaler, including a canister movable relative to a base that has a dose counter in the base, where the base retains the canister and an actuation member in the base which is activated by the canister during compression increments the counter.

The examiner maintains that slight design variations such as variations in the shape of canister support formations, and how close these support formations are to an actuation member are not important functional differences.

In addition, the term "adjacent" allows some leeway for components that are nearby. The claim limitations do not amount to a patentable distinction since the prior art inhalers of Morton and Davies function and count in almost exactly the same way. The applicant has not shown that the level of nearness between support formations and an actuation member is functionally crucial.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

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Claims 1-10 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Morton et al. (US 2005/0087191) in view of Davies et al. (US 2006/0107949).

Re claim 1-3: Morton is an inhaler for metered dose inhalation. There is a main body holding a medicament canister, and a dose counter.

See notably figures 74, 77, 78 and 79 and paragraphs 0276 and 0293-0295. An actuator member 7070 of a dose counter has a protruding post portion 7074 which goes through an aperture 7156 (figure 77) such that it goes in the canister housing to make contact with the medicament canister when the medicament canister moves downward.

For further clarification, a distinction should be drawn between two major embodiments in Morton. A first type of embodiment, exemplified by figure 31, has a counter/indicator cap that sits atop a canister. A second type of embodiment exemplified by figures 74 and 93 has a counter/indicator cap below the canister with an actuator pointing upward. It is this arrangement that the examiner focuses on. The first embodiment is apparently completely different, and to be ignored. (There are further sub-embodiments within these, but this discussion is about the second category of embodiments).

Regarding inwardly protruding canister support formations, Davies et al. shows these (see figures 6 and 13, ref. 50 and para 0080). It would be obvious to include these in Morton for greater support and stability.

The applicant makes some argument regarding the limitation that the support formations are 'directly adjacent the actuation member'; the examiner maintains that this can be met if 'adjacent' is taken as 'near to'. The term 'adjacent' gives considerably leeway and is met, since the various components in question are all very near to one another in the prior art.

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Re claims 4 and 6: See para 0302 and fig. 94, ref 8304. In some embodiments there are ribbed portions extending vertically that help support and hold the canister.

Re claim 5: See figures 90 and 94, and note that there is a stepped structure inside the receiving portion that receives the canister.

Re claim 7: If the vertical ridges 8304 at figure 94 (which hold and maintain the position of the canister) are taken as support rails, then the claim limitation is met. It can be seen that they are on opposite sides and face each other.

Re claims 8-10: Steps and a tapering effect in the canister support structure can be seen in several places. In figure 74, the housing 200 that contains the canister 12 appears to show a taper at the point nearest the viewer.

Similarly canister holders in figures 90 and 94 have a tapering arrangement.

Finally, the examiner argues that the precise shapes are, to some extent, a matter of design choice since there is more than one equivalent way to have internal support structures hold the canister in position. Having a gap in the canister housing that is filled by support rails is not functionally better or worse than having a canister housing with less of a gap, more closely conforming to the shape of the housing and obviating the need for the type of rails in the instant invention.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL HESS whose telephone number is (571)272-2392. The examiner can normally be reached on 9:00 AM - 5:00 PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Lee can be reached on (571) 272-2398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DANIEL HESS/  
Primary Examiner, Art Unit 2876